HRQL studies in clinical trials, and how to evaluate the validity of HRQL claims, for appropriate decision-making.
METHOD: A guidance document and a checklist have been designed following a literature search and using the experience of the ERIQA group's members, i.e., HRQL researchers, pharmaceutical industry representatives, academic people, and reviewers for regulatory authorities.
RESULTS: The guidance document reviews the major issues of HRQL assessment in clinical trials, and especially practical considerations such as: selection of an HRQL questionnaire (i.e., minimal properties required, validation of translated versions); implementation of a HRQL assessment (i.e., training of study personnel, mode of administration, eligibility criteria, data collection, prevention of missing data, respondent burden, multicenter trial); statistical analysis (i.e., justification of the sample size, handling of missing data, handling of multiple statistical tests), and interpretation. For each issue, recommendations are made, even when there is no definite answer (e.g., interpretation of results). All the issues to be prespecified in the research protocol are mentioned. The checklist summarizes all the issues. It is intended to help both regulatory authority reviewers in performing their clinical trial reviews and sponsors and investigators in conducting a clinical trial with HRQL data and writing the study report.
CONCLUSION: The final objective is to reach a large European agreement upon this guidance document, to improve the quality of HRQL studies and to convince European regulatory authorities of the usefulness and scientific value of HRQL assessment.

TPQ4

A EUROPEAN EQ-5D VALUE SET. MYTH OR REALITY?

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OBJECTIVES: To harmonize VAS values resulting from 11 studies in 6 countries (England, Finland, Germany, The Netherlands, Spain and Sweden) using the EQ-5D valuation questionnaire, developed by the EuroQol Group. The aim is to make available a European EQ-5D value set and to gain insight into the influences resulting from the prevailing differences in methodology and sample characteristics.
METHODS: The database constructed for this research project contains data on more than 110.000 health states from 8370 respondents. Appropriate transformation was applied to deal with ceiling and floor effects. Regression models and a single value decomposition were applied to explore the differences between the valuations in the 11 samples and the influences of background variables on the VAS values of a subset of 18 health states. Multilevel regression analysis on data of 49 health states was conducted to take into account characteristics at the individual respondent level while testing the impact of health state characteristics on the value set.
RESULTS: In general, the impact of the background variables such as age and experience of illness on the VAS valuations appeared to be modest. Differences in study methodology have a higher impact on the VAS values but differences in the health states themselves were found to be the major determinant of VAS values.
CONCLUSIONS: When corrected for the influence of the background variables, the VAS values from the 6 countries showed a remarkable agreement. Differences can be attributed to differences in survey methodology and sample characteristics rather than 'cultural' aspects. By using a simple instrument, ie., the EQ-5D valuation questionnaire, it seems that an internationally consistent EQ-5D value set can be established.

TPQ5

MAPI RESEARCH INSTITUTE HEALTH-RELATED QUALITY OF LIFE OUTCOMES DATABASE (IQOD) PROJECT

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BACKGROUND: Health-related Quality of Life (HRQL) of patients is increasingly being used as an endpoint in multinational studies. In this era of international collaboration, there is a critical need for improved interpretation of HRQL studies and the confirmation of conceptual equivalence of linguistically adapted HRQL instruments used in multinational studies. In order to facilitate these two objectives, Mapi Research Institute has launched the development of IQOD.
OBJECTIVES: The primary objective of the IQOD project is the development of an international database that will contain HRQL, socio-demographic, and clinical data from multinational HRQL studies. Once this database is developed the following objectives can be realised: (1) Development of reference values to facilitate interpretation of scale scores and making it possible to estimate the relative burden of various medical and psychological conditions across populations and across disease severities; (2) Evaluation of the conceptual equivalence of linguistically adapted HRQL instruments used in multinational studies; (3) Development of item banking.
METHODS: During the initial phase of this project, data will be obtained from sponsors of international studies in which linguistically valid HRQL questionnaires, provided by Mapi Research Institute, were administered. There are 13 instruments included in the initial phase of this project. The first step of the initial phase is the development of reference values for the Women's Health Questionnaire (WHQ) and the Minnesota Living with Heart Failure Questionnaire (MLHF).
RESULTS: Results of the initial phase will be presented upon completion of analysis.